

June 27, 2002

Proposed Monograph Changes

Add to 21 CFR 355.10(a)(3), between current (ii) and (iii), as a new paragraph:

An aqueous solution of sodium fluoride acidulated with a mixture of benzoic acid and sodium benzoate to a pH of approximately 4.2, which yields an effective fluoride concentration of 0.01 percent.

Add to 21 CFR 355.50(d)(2), after current (ii), as a new paragraph:

For acidulated sodium fluoride solution containing 0.01 percent fluoride ion identified in §355.10(a)(3) (TBD). Adults and children 12 years or older: Use twice a day morning and night after brushing your teeth with a toothpaste. Rinse full strength for 30 seconds with 20ml (2/3 fluid ounce or 4 teaspoonfuls). Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing.